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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/521,411 | 09/01/2005 | Shunichi Kuroda | 62703(70904) | 9056 |
| 21874 7590 05/01/2007 EDWARDS ANGELL PALMER & DODGE LLP P.O. BOX 55874 BOSTON, MA 02205 | | | EXAMINER SAJJADI, FEREDOUN GHOTB | |
| | | | ART UNIT 1633 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|---|--------------------------------------|--|
| Office Action Summary | Application No. 10/521,411 | Applicant(s) KURODA ET AL. | |
| | Examiner Fereydoun G. Sajjadi | Art Unit 1633 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6,7 and 9-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6,7 and 9-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>8/23/06 & 12/19/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Status

Applicants' response of January 30, 2007, to the non-final action dated May 3, 2006 has been entered. Claims 1, 6, 7, 9, and 10 have amended. Claims 2-5 and 8 have been cancelled, and claims 11 and 12 are newly added. Claims 1, 6, 7 and 9-12 are pending in the application and under current examination.

Information Disclosure Statement

The translated non-patent literature document titled: Viral Infection Model Using Immunodeficiency Mouse, has been considered by the examiner, and acknowledged in form PTO/SB/O8. However, the information disclosure statement filed 12/19/2006 fails to comply with 37 CFR 1.98(a)(3)(ii), which requires a copy of the translation if a written English-language translation of a non-English-language document, or portion thereof, is within the possession, custody, or control of, or is readily available to any individual designated in § 1.56(c). It has been placed in the application file, but the information referred to therein has not been fully considered, since JP-8-511937 is in the Japanese language.

New Claim Objections

Claim 11 is objected to for reciting "inclaim" in the second line. A space is required between the words "in" and "claim".

New Claim Rejections - 35 USC § 112- Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Applicants' claim amendments have necessitated the following new grounds of rejection.

Claims 10-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10 and 12 are unclear in the recitation of "mouse model, characterized by comprising the steps of", because it is not clear whether said characterization is in reference to the production method or the mouse model. Further, a mouse model may not be characterized by steps. The inclusion of "characterized by" in the claims is unnecessary.

Claim 12 is further unclear, for reciting a human cirrhosis tissue affected with cirrhosis. As cirrhotic tissue must necessarily be affected by cirrhosis, it is not clear how such tissue can be further affected by cirrhosis. A second recitation of cirrhosis is redundant.

Claim 11 recites the limitation "the hepatic cirrhosis tissue" in the second line. There is insufficient antecedent basis for this limitation in this claim or in claim 1 from which this claim depends.

Response & New Claim Rejections - 35 USC § 112-Scope of Enablement

Applicants' claim amendments have necessitated the following new grounds of rejection.

Claims 1-10 stand rejected under 35 U.S.C. § 112, first paragraph, in the previous office action dated May 3, 2006, for lacking an enablement for the full scope of the claimed invention. The cancellation of claims 2-5 and 8 renders their rejection moot. In view of Applicants' amendment of the claims to limit the cirrhosis animal model to a scid mouse, the grounds of rejection for any animal or any scid animal are hereby withdrawn. The rejection set forth on pages 2-6 of the previous office action dated May 3, 2006 is maintained for claims 1, 6, 7, 9 and 10, and further applied to new claims 11 and 12, for reasons set forth in the following commentary.

Applicants state that the claims have been amended to add a limitation that the human cirrhosis tissues are transplanted to a kidney of a scid mouse. Applicants' arguments have been fully considered, but are not found persuasive. Base claim 1 as amended, is no longer limited to the transplantation of human cirrhotic hepatic tissue, and is directed instead to a cirrhosis scid mouse model characterized in that a human cirrhosis tissue is transplanted in a kidney of a scid mouse. However, the claim language is not commensurate with the enabled scope of the invention (i.e. the transplantation of human Child A cirrhotic liver tissue), as human cirrhosis broadly embraces any type of fibrosis, such as pulmonary fibrosis of the lung. The instant specification is silent on the transplantation of any human cirrhotic tissues having any stage of

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advancement for cirrhosis, other than Child A liver tissue to the kidney of a scid mouse. The prior art is also devoid of any teachings regarding the transplantation of non-hepatic cirrhotic tissues to a mouse kidney. As such, a person of skill in the art would need to engage in further undue experimentation to determine the efficacy of transplanting human non-hepatic cirrhotic tissues, or hepatic tissue that is more advanced than the Child A classification, especially in view of the instant specification's teaching that tissue affected by more severe cirrhosis would be difficult to transplant (p. 6, second paragraph).

Thus, the previous rejection of the claims is maintained for claims 1, 6, 7, 9 and 10, and is further applied to newly added claims 11 and 12 for reasons of record and the foregoing discussion.

Response and New Claim Rejections - 35 USC § 102

Applicants' claim amendments have necessitated the following new grounds of rejection.

Claims 1 and 10 stand rejected under 35 U.S.C. 102(e) as being anticipated by Kay et al. (U.S. Patent No: 6,660,905, filed Jul. 12, 2000). The rejection set forth on p. 7 of the previous office action dated May 3, 2006 is maintained for claims 1 and 10 and is applied to newly added claim 11, for reasons of record.

Applicants disagree with the rejection, arguing that the invention as now claimed in amended claim 1 relates to a scid mouse model in which human cirrhosis tissues have been transplanted in the kidney. Applicants further argue that human cirrhosis tissues are dysfunctional tissues and that Kay et al. merely teach an animal model for human disorders, using functional tissues, without disclosing anything about an animal model for human disorders using dysfunctional tissues. Applicants arguments have been fully considered, but not found persuasive.

In response it should be noted that the degree of dysfunctionality of cirrhotic tissue is dependent upon the degree of progression of cirrhosis, in accordance with the Child-Pugh classification. The instant specification and claim 9 teach the transplantation of Child A liver tissue, i.e. mild cirrhosis or "slightly affected with cirrhosis". The instant specification states that a Child's C cirrhosis tissue that is "severe cirrhosis tissue" would be difficult to transplant (p. 6,

second paragraph). None the less, Kay et al. state: "The animals of the invention can also be used to study human liver development and function, both normal and abnormal, e.g. malignant or genetically altered", that can be introduced and maintained in the animal models (column 18, lines 50-54). Kay et al. further teach their animal model has broad applicability in the study of degenerative and metabolic diseases of the human liver and provide an animal model for human disorders involving exposure to chemicals or toxins, such as alcoholic cirrhosis (column 3). Thus, dysfunctional tissue transplantation that includes diseased or cirrhotic liver tissue is embraced by the teachings of Kay et al. Therefore, the foregoing statements explicitly teach an animal model of cirrhosis that include the study of abnormal cirrhotic liver tissues.

Hence, the rejection is maintained for reasons of record and expanded upon by the commentary given above.

Response and New Claim Rejections - 35 USC § 103

Applicants' claim amendments have necessitated the following new grounds of rejection.

Claims 6, 7 and 9 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Kay et al., and further in view of Habu et al. (U.S. Patent Publication No.: 2004/0016007, filed May 15, 2001). The rejection set forth on pp. 8-10 of the previous office action dated May3, 2006 is maintained for claims 6, 7 and 9 and is applied to newly added claim 12, for reasons of record.

Applicants disagree with the rejection, arguing that the invention as now claimed in amended claims 1, 10 and 12 recite the use of dysfunctional tissues and that Habu et al. do not disclose or suggest an animal model for human disorders using dysfunctional tissues either. Applicants' arguments have been fully considered, but not found persuasive.

Applicant has referred to a foregoing publication, Virus, 49(1), 33-39 (1999). It is not clear how this citation relates to the publications of Kay and Habu. Regarding the recitation of dysfunctional tissues, it is noted that while the instantly amended claims recite cirrhosis tissues, they do not recite the use of dysfunctional tissues. Further, the functionality of transplanted tissues, as relating to the Kay et al. reference was addressed above. As Habu et al. are not required to teach each and every limitation of the claims in an obviousness rejection, the rejection is maintained for reasons of record and the expanded commentary given above.

Conclusion

Claims 1, 6, 7, and 9-12 are not allowed.

Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst William Phillips, whose telephone number is **(571) 272-0548**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fereydoun G. Sajjadi whose telephone number is **(703) 272-3311**. The examiner can normally be reached Monday through Friday, between 7:00-4:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on **(571) 272-0739**. The fax phone number for the organization where this application or proceeding is assigned is **(571) 273-8300**. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

For all other customer support, please call the USPTO Call Center (UCC) at **(800) 786-9199**.

Fereydoun G. Sajjadi, Ph.D.
Examiner, USPTO, AU 1633



ANNE M. WEHBE' PH.D
PRIMARY EXAMINER

